

REMARKS

The Office Action mailed October 8, 2003 has been carefully considered by applicant.

Herewith applicant submits an amended drawing figure 9. The amended drawing figure properly denotes the "elongated barrel" with reference number 44. No new matter has been added by this amendment.

By the present amendment, the specification has been amended to correct several typographical errors. Specifically, the "sponge holder" noted on page 10, line 16 is denoted in the figures as reference numeral "14a". The specification has been amended to properly correspond to the figures. Also, the "elongated barrel" noted on page 14, line 13 is now denoted in the figures as reference numeral 44. The specification has been amended to properly correspond to the figures. No new matter has been added by these amendments.

By the present amendment, claims 1, 3-7, 17, 23, 25, 27, 33, 35 and 37 are amended. Claims 38-40 are added. Claims 2, 24, 26, 28 and 29 are canceled.

Claim Rejections Under 35 USC §102(b)

In the Office Action, claims 1, 8-10, 12-16, 23 and 34 have been rejected under 35 USC §102(b) as being anticipated by Leonard et al U.S. Patent No. 5,945,076. Claims 1, 8-10, 12 and 17 have been rejected under 35 USC §102(b) as being anticipated by Ebling et al U.S. Patent No. 5,569,161. Claims 1, 8-10, 13-23 and 26 have been rejected under 35 USC §102(b) as being anticipated by Boulet WO 94/26633. Claims 1, 8 and 34 have been rejected under 35 USC §102(b) as being anticipated by Yamada U.S. Patent No. 5,437,836.

Present Application Claim 1

Claim 1 has been amended to more clearly define the present invention and render the same allowable over the applied references. Claim 1 now recites a container for sterilizing an object. The container is adapted to receive the object and has a first end with an opening to allow positioning of the object in the container and a second end located generally opposite the first end. Closure means are for closing the opening in the first end

and include a vapor permeable sterility barrier. At least a portion of the container is collapsible or deformable such that the first end and the second end are moved relatively towards each other to extend the object toward the opening in the first end.

Claim 1 is not anticipated by Leonard et al 5,945,076 because this reference does not, among other things, teach or suggest closure means comprising a vapor permeable sterility barrier. Rather, Leonard et al '076 teaches merely a container (12) for storing a toilet brush (15) that is constructed in two parts: a disinfectant fluid container (12) and a brush container (14). A bellows section (26) is vertically compressible and a valve (28) allows a volume of fluid to immerse the brush (57) and thereby clean the brush (57). Column 6, lines 3-11. Wall (88) does not include a closure means including a vapor permeable sterility barrier. Instead, wall (88) includes air-intake (89) and air escape (92) to permit air into and out of the brush container (14). Nowhere in Leonard et al '076 is there taught or suggested a container including closure means comprising a vapor permeable sterility barrier.

Claim 1 is not anticipated by Ebling et al U.S. Patent No. 5,569,161 because this reference does not, among other things, teach or suggest closure means comprising a vapor permeable sterility barrier. In contrast, Ebling et al '161 teaches a sterile sleeve (24) for an endoscope. The sterile sleeve (24) has a window (38) for a fiber optic image bundle (14). The sterile sleeve and the window cooperate to isolate the nonsterile fiber optic image bundle from the patient and thereby prevent transmission of contagions from the fiber optic image bundle to the patient. Column 2, lines 28-42. Nowhere in Ebling et al '161 is there taught or suggested closure means comprising a vapour permeable sterility barrier.

Claim 1 is not anticipated by Boulet 'WO 94/26633 because this reference does not, among other things, teach or suggest closure means comprising a vapor permeable sterility barrier. In contrast, Boulet '633 merely teaches a container that is hermatically closed by deforming a second part of the container to contact the first part of the container. There is no mention in Boulet '633 of any type of closure means comprising a vapour permeable sterility barrier.

Claim 1 is not anticipated by Yamada '836 because this reference does not, among other things, teach or suggest closure means comprising a vapor permeable sterility barrier. In contrast, Yamada '836 merely teaches a vertically expandable storage container (2). The container has an upper cover (3) integrally formed with an outlet (8) and an inlet (7) which communicates with the interior of the container. However, the container is not in any way provided with a closure means comprising a vapour permeable sterility barrier.

Claims 8-10, 12-22 and 34

Claims 8-10, 12-22 and 34 depend directly or indirectly from claim 1 and are thus believed allowable for the reasons stated above, as well as for the detailed subject matter recited therein.

Claim 23

Claim 23 has been amended to more clearly define the invention and render the same allowable over the applied references. Claim 23 now recites a container for sterilizing an object. The container has an internal volume for receiving the object, an opening through which the object can be inserted into the container, and closure means closing the opening. The closure means comprises a vapor permeable sterility barrier. The container has a first end and a second end and a portion between the first end and the second end that is breakable to enable separation of the container into at least two parts, thereby to expose the object.

Similar to arguments made above, claim 23 is not anticipated by Leonard et al U.S. Patent No. 5,945,076 because this reference, among other things, does not teach or suggest closure means for closing the opening which comprise a vapor permeable sterility barrier. Leonard et al '076 further does not teach or suggest a portion between first and second ends that is breakable to enable separation of the container into at least two parts.

Claim 23 is also not anticipated by Boulet WO94/26633 because this reference, among other things, does not teach or suggest closure means comprising a vapor permeable sterility barrier or a portion that is breakable to enable separation of the container into at least two parts.

Claim Rejections Under 35 USC §103(a)

Claims 1-37 have been rejected under 35 USC §103(a) as being unpatentable over Kowanko U.S. Patent No. 6,162,395 in view of the Schuster patent referred to as U.S. Patent No “4,002,324” in the Office Action but more properly “4,022,324”.

Present Application Claim 1

Claim 1 is not rendered obvious by either Kowanko U.S. Patent No. 6,162,395 or Schuster U.S. Patent No. 4,022,324, or their combined teachings, for the following reasons. Neither of these references teach or suggest a container that is collapsible or deformable whereby the first and second ends are moved relatively towards each other to extend the object towards the opening in the first end. As such, neither of the cited references teaches the combination of closure means comprising a vapor permeable sterility barrier with a container that is collapsible or deformable whereby the first and second ends are moved relatively towards each other to extend the object towards the opening in the first end. This combination of elements is not obvious based upon the combined teaching of the prior art and the invention of claim 1 could not have been achieved by making mere routine steps from the teachings of the cited prior art.

Kowanko ‘395 discloses a hollow sterilizing cassette package that includes a body (10) and a removable lid (11). The cassette is formed with vapor permeable areas (34) and (36) which permit the entry and exit of sterilant gases from the cassette. The cassette is divided into two volumes that respectively have differently sized vapor permeable areas (34) and (36) such that a difference in gas pressure is established between the two components. The vapor pressure difference drives the movement of sterilant gas from one compartment to the other, thereby sterilizing a lumen that traverses both compartments. The cassette shown in Fig. 1 and other embodiments described in Kowanko ‘395 do not incorporate a portion of the container that is collapsible or deformable such that the first and second ends are moved relatively towards each other to extend the object towards the opening in the first end.

Schuster ‘324 discloses a sealed container for storing medical articles in a sterile condition. The container is described in the passage from line 34 in column 3 to line

35 in column 4. The container (10) comprises “a relatively rigid, thermoplastic tray (12) having a flexible, removable cover (14).” The cover (14) includes a breathable membrane (32) that is “essentially completely impermeable to bacteria but unlike the panels, is highly permeable to the sterilizing vapor”. It appears, however, that the article is removed from the container by removing the entire cover (14) and retrieving the article from the tray.

In contrast to the cited references, the invention of claim 1 provides a container that is collapsible or deformable such that the first end and the second end are moved relatively towards each other to extend the object towards the opening in the first end. This arrangement provides significant advantages that are not provided by the devices shown in the prior art. As stated in the present application, the unique combination of elements in claim 1 provides a collapsible or deformable container which advantageously allows the equipment inside the container to remain sterilized and yet be easily accessed during surgical operation.

In particular, in use in a surgical operation, the nonsterile nurse removes the closure and then collapses or deforms the collapsible or deformable portion of the container. Consequently, the sterile piece of medical or surgical equipment inside the container is at least partially exposed and the sterile nurse can grasp the exposed part and remove the sterile equipment from the container. The container of the present invention allows the sterilized equipment to be removed therefrom without the nonsterile nurse having to touch the sterile inner part of the container and the sterile equipment inside the container. The sterile nurse does not have to touch the nonsterile outer surface of the container. Line 26, page 6-line 4, page 7.

The prior art references, including Kowanko '395 and Schuster '324 do not teach or suggest such a container that promotes such sterile storage, handling and distribution of the container. The advantages described above are provided by the unique combination of elements claimed in claim 1, which are not taught or suggested by the prior art.

Claims 3-7

Claims 3-7 depend directly or indirectly from claim 1 and are thus believed allowable for the reasons stated above, as well as for the subject matter recited therein. More particularly, claims 3-7 further define various aspects of the closure means and/or the

vapor permeable sterility barrier. As stated above, these elements are not taught or suggested by the prior art and thus claims 3-7 are believed allowable.

Claims 8-22

Claims 8-22 depend directly or indirectly from claim 1 and are thus believed allowable for the same reasons, as well as for the detailed subject matter recited therein.

Claim 23

As stated above, amended claim 23 now recites a container for sterilizing an object. The container has an internal volume for receiving the object, an opening through which the object can be inserted into the container, and closure means closing the opening. The closure means comprises a vapor permeable sterility barrier. The container has a first end and a second end and a portion between the first end and the second end that is breakable to enable separation of the container into at least two parts, thereby to expose the object.

Similar to the arguments made for claim 1, claim 23 is not rendered obvious by Kowanko '395 or Schuster '324, or a combination thereof. Neither of these references teach or suggest a container that includes a portion that is breakable to enable separation of the container into at least two parts, thereby to expose the object in the container. Further, neither Kowanko '395 nor Schuster '324 teach or suggest a container having the combination of closure means comprising a vapor permeable sterility barrier and a portion that is breakable to enable separation of the container into at least two parts, thereby to expose the object. This combination provides many advantages, some of which are highlighted above in the arguments regarding claim 1. The prior art references neither teach nor suggest this unique combination of elements. As such, claim 23 is believed allowable over the applied references.

Claims 25, 27 and 30-33

Claims 25, 27 and 30-33 depend directly or indirectly from claim 23 and are thus believed allowable for the reasons stated above, as well as for the detailed subject matter cited therein.

Claim 35

By the present amendment, claim 35 has been amended to more clearly define the subject matter of the present invention and render the same allowable over the applied references. Claim 35 recites a method for sterilizing an object comprising the steps of placing the object into a container having an opening through which the object is inserted. The container has first and second ends and at least a portion which is deformable or collapsible by moving a first end of the container relatively towards a second end of the container, closing the opening with a vapor permeable sterility barrier and placing the container in a sterilizing environment for sufficient time to sterilize the object.

Neither Kowanko '395 nor Schuster '324 teach or suggest a container that is deformable or collapsible by moving a first end of the container relatively towards a second end of the container. With reference to the arguments made above regarding claim 1, the devices taught by Kowanko '395 and Schuster '324 do not provide deformable or collapsible sections. In addition, these references do not render obvious the combination of a vapor permeable sterility barrier and a deformable or collapsible portion of the container. This unique combination provides many advantages highlighted above, and is not rendered obvious by the applied references.

Claim 37

Claim 37 depends directly from claim 35 and is also believed allowable.

New Claims 38-39

New claims 38-39 are presently added to further define inventive subject matter of claims 1 and 17 from which they depend and are believed allowable for the same reasons as the latter claims.

Independent Claim 40

Claim 40 has been added to further define subject matter of the present invention. Claim 40 is similar to claim 35 in that it recites a method for sterilizing an object comprising the steps of placing the object into a container having an opening through which

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the object is inserted. The container has first and second ends and at least a portion which is deformable or collapsible by relatively moving a first end of the container and a second end of the container toward each other. The opening is closed with a vapor permeable sterility barrier. Similar to the reasoning set forth above for claim 1 and claim 35, the cited references do not render this combination of elements obvious.

In addition, claim 40 recites placing the container in a sterilizing environment for sufficient time to sterilize the object, wherein the object is removed from the container by collapsing or deforming the collapsible portion to thereby reduce an inner volume of the container and force the object to break open the vapor permeable sterility barrier and extend at least partly out of the container. This arrangement is neither taught nor suggested by the prior art. As such, claim 40 is believed allowable.

Conclusion

The present application is thus believed in condition for allowance with claims 1, 3-23, 25, 27, 30-35 and 37-40. Such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP



Peter T. Holsen
(Reg. No. 54,180)

100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
(414) 271-7590
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